

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Rao et al.

Serial No.: To be assigned

Filed: February 27, 2004

For: PERSISTENT EXPRESSION OF
CANDIDATE MOLECULE IN
PROLIFERATING STEM AND
PROGENITOR CELLS FOR DELIVERY OF
THERAPEUTIC PRODUCTS

Examiner: To be assigned

Group Art Unit: To be assigned

Attorney Docket No.: 2923-5456.1US

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INFORMATION DISCLOSURE STATEMENT

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Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO/SB/08 be considered by the Examiner and made of record. Copies of U.S. patents are not being submitted pursuant to Pre-OG Notices <<http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/idswouscopies.htm>> (visited 9/15/2003). Copies of foreign patent documents and non-patent literature are enclosed pursuant to 37 C.F.R. § 1.98(a)(2).

In accordance with 37 C.F.R. § 1.97(g) and (h), filing of this Information Disclosure Statement is not to be construed as a representation that a search has been made or an admission

that the information cited herein is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b). Further, no representation is made by Applicants herein that no other possible material information as defined in 37 C.F.R. § 1.56(b) exists.

U.S. Patent Documents

<u>U.S. Patent No.</u>	<u>Publication Date</u>	<u>Patentee</u>
US- 2002/0012660 A1	01/31/2002	Colman et al.
US- 2002/0037281 A1	03/28/2002	Davidson et al.
US- 4,350,687	09/21/1982	Lipton et al.
US- 4,766,073	08/23/1988	Murray et al.
US- 4,801,542	01/31/1989	Murray et al.
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US- 5,180,820	01/19/1993	Barde et al.
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US- 5,399,346	03/21/1995	Anderson et al.
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US- 5,627,059	05/06/1997	Capecchi et al.
US- 5,631,153	05/20/1997	Capecchi et al.
US- 5,641,670	06/24/1997	Treco et al.
US- 5,650,148	07/22/1997	Gage et al.
US- 5,750,376	05/12/1998	Weiss et al.
US- 5,753,491	05/19/1998	Major et al.
US- 5,753,505	05/19/1998	Luskin
US- 5,762,926	06/09/1998	Gage et al.
US- 5,830,651	11/03/1998	Cauley et al.
US- 5,849,553	12/15/1998	Anderson et al.
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US- 5,928,638	07/27/1999	Uchida et al.
US- 5,928,947	07/27/1999	Anderson et al.
US- 5,968,502	10/19/1999	Treco et al.
US- 5,981,214	11/9/1999	Skoultchi
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US- 6,093,802	07/25/2000	Lin et al.
US- 6,139,835	10/31/2000	Kucherlapati et al.
US- 6,204,061 B1	03/20/2001	Capecchi et al.
US- 6,221,376 B1	04/24/2001	Lin et al.
US- 6,251,669 B1	06/26/2001	Luskin
US- 6,270,989 B1	08-07-2001	Treco et al.
US- 6,312,957 B1	11/06/2001	Einerhand et al.
US- 6,339,065 B1	01/15/2002	Cooper
US- 6,355,239 B1	03/12/2002	Bruder et al.
US- 6,355,241 B1	03/12/2002	Selden et al.
US- 6,362,319 B1	03/26/2002	Lin et al.
US- 6,436,387 B1	08/20/2002	Bauer et al.

Foreign Patent Documents

<u>Document No.</u>	<u>Publication Date</u>	<u>Patentee</u>
WO 96/04397	02/15/1996	Anvret et al.
08298219 (Japanese Abstract)	05/12/1998	Mitsui

Other Documents

AGAH et al., "Gene Recombination in Postmitotic Cells," J. Clin. Invest., July 1997, pp. 169-79, Vol. 100, No. 1.

ARBONES et al., "Gene Targeting in Normal Somatic Cells: Inactivation of the Interferon- γ Receptor in Myoblasts," Nature Genetics, Vol. 6, Jan. 1994, pp. 90-159).

BUNZ et al., "Targeted Inactivation of p53 in Human Cells Does Not Result in Aneuploidy," Cancer Research 62, Feb. 15, 2002, pp. 1129-1133.

CONG et al., "Human Telomerase and Its Regulation," Microbiol. Mol. Biol. Rev., Sept. 2002, pp. 407-425.

COPELAND et al., "Recombineering: A Powerful New Tool for Mouse Functional Genomics," Nature Reviews/Genetics, Vol. 2, Oct. 2001, pp. 769-779.

COURT et al., "Genetic Engineering Using Homologous Recombination," Annu. Rev. Gener. 2002, 36:361-88.

HANSON et al., "Analysis of Biological Selections for High-Efficiency Gene Targeting," Mol. Cell. Biol., Jan. 1995, pp. 45-51.

HANSON et al., "Effects of c-myc Expression on Cell Cycle Progression," Mol. Cell. Biol., Sept. 1994, pp. 5748-5755.

LINNEY et al., "DNA Fragments from F9 PyEC Mutants Increase Expression of Heterologous Genes in Transfected F9 Cells," Cell, December 1983, pp. 693-99, Vol. 35.

PROUTY et al., "A Cell Culture Model System for Genetic Analyses of the Cell Cycle by Targeted Homologous Recombination," Oncogene (1993) 8, pp. 899-907.

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RAO et al., "Glial-Restricted Precursors Are Derived from Multipotent Neuroepithelial Stem Cells," *Developmental Biology*, 188:48-63, 1997.

SEDIVY, John M., "Can Ends Justify the Means?: Telomeres and the Mechanisms of Replicative Senescence and Immortalization in Mammalian Cells," *Proc. Natl. Acad. Sci. USA*, Vol. 95:9078-9081, Aug. 1998.

SOMMER et al., "Neural Stem Cells and Regulation of Cell Number," *Progress in Neurobiology*, 66:1-18 (2002).

THOMAS et al., "Site-Directed Mutagenesis by Gene Targeting in Mouse Embryo-Derived Stem Cells," *Cell*, November 6, 1987, pp. 503-512, Vol. 51.

WU et al., "Isolation of a Glial-Restricted Tripotential Cell Line From Embryonic Spinal Cord Cultures," *GLIA* 38:65-79 (2002).

YANEZ et al., "Differential Effects of Rad52p Overexpression on Gene Targeting and Extrachromosomal Homologous Recombination in a Human Cell Line," *Nucleic Acids Research*, 2002, Vol. 30, No. 3, pp. 740-748.

YANEZ et al., "Influence of DNA Delivery Method on Gene Targeting Frequencies in Human Cells," *Somatic Cell and Molecular Genetics*, Vol. 25, No. 1, 1999, pp. 27-31.

YANEZ et al., "Therapeutic Gene Targeting," *Gene Therapy*, 1998, 5, pp. 149-159.

YANEZ et al., "Uracil Incorporation Into a Gene Targeting Construct Reduces the Frequency of Homologous and Nonhomologous Recombinants in Human Cells," *Mutation Research* 461, 2000, pp. 157-162.

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56 & 1.175, Applicants offer hereby identifies the following listed copending applications naming the same inventor(s):

Attorney Docket No.:	2923-6033US
Serial No.:	60/496,830
Filing Date:	8/21/2003
Title:	GENETICALLY MODIFIED SOMATIC CELLS FOR SUSTAINED SECRETION OF LYSOSOMAL PROENZYMES DEFICIENT IN LYSOSOMAL STORAGE DISORDERS

Attorney Docket No.: 2923-5456.1US

This Information Disclosure Statement is filed within three (3) months of the filing date of the above-identified application, and no certification pursuant to 37 C.F.R. § 1.97(c) or a fee pursuant to 37 C.F.R. § 1.17(p) is required.

Respectfully submitted,



Krista Weber Powell
Registration No. 47,867
Attorney for Applicant(s)
TRASKBRITT, P.C.
P.O. Box 2550
Salt Lake City, Utah 84110-2550
Telephone: 801-532-1922

Date: February 27, 2004
KWP/bv

Enclosures: Form PTO-1449 or PTO/SB/08
Cited Documents

Document in ProLaw

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 4

Complete if Known

Application Number	To be assigned
Filing Date	
First Named Inventor	Rao et al.
Group Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	2923-5456.1US

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
		US- 2002/0012660 A1	01/31/2002	Colman et al.	
		US- 2002/0037281 A1	03/28/2002	Davidson et al.	
		US- 4,350,687	09/21/1982	Lipton et al.	
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		US- 5,641,670	06/24/1997	Treco et al.	
		US- 5,650,148	07/22/1997	Gage et al.	

FOREIGN PATENT DOCUMENTS

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		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
		WO 96/04397	02/15/1996	Anvret et al.		

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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet

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of

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Application Number	To be assigned
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First Named Inventor	Rao et al.
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		US- 5,753,491	05/19/1998	Major et al.	
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		US- 6,355,241 B1	03/12/2002	Selden et al.	
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		US- 6,436,387 B1	08/20/2002	Bauer et al.	

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		08298219 (Japanese Abstract)	05/12/1998	Mitsui		

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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		AGAH et al., "Gene Recombination in Postmitotic Cells," J. Clin. Invest., July 1997, pp. 169-79, Vol. 100, No. 1.	
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		LINNEY et al., "DNA Fragments from F9 PyEC Mutants Increase Expression of Heterologous Genes in Transfected F9 Cells," Cell, December 1983, pp. 693-99, Vol. 35.	
		PROUTY et al., "A Cell Culture Model System for Genetic Analyses of the Cell Cycle by Targeted Homologous Recombination," Oncogene (1993) 8, pp. 899-907.	
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		RAO et al., "Glial-Restricted Precursors Are Derived from Multipotent Neuroepithelial Stem Cells," Developmental Biology, 188:48-63, 1997.	
		SEDIVY, John M., "Can Ends Justify the Means?: Telomeres and the Mechanisms of Replicative Senescence and Immortalization in Mammalian Cells," Proc. Natl. Acad. Sci. USA, Vol. 95:9078-9081, Aug. 1998.	

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		SOMMER et al., "Neural Stem Cells and Regulation of Cell Number," Progress in Neurobiology, 66:1-18 (2002).	
		THOMAS et al., "Site-Directed Mutagenesis by Gene Targeting in Mouse Embryo-Derived Stem Cells," Cell, November 6, 1987, pp. 503-512, Vol. 51.	
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		YANEZ et al., "Differential Effects of Rad52p Overexpression on Gene Targeting and Extrachromosomal Homologous Recombination in a Human Cell Line," Nucleic Acids Research, 2002, Vol. 30, No. 3, pp. 740-748.	
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